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skeletal dynamics

510(k) Summary of Safety and Effectiveness
Skeletal Dynamics Sterilization Trays

July 22, 2010

DEC - 7 2010

Submitter:
Skeletal Dynamics, LLC
8905 SW 87 Avenue
Suite 102
Miami, FL 33176
Tel: (305) 596-7585
Fax: (305) 596-7591
Contact: Ana Escagedo / Vice President Quality & Regulatory Affairs
Email: aescagedo@skeletaldynamics.com

FDA Establishment Registration Number: Pending

Trade Name, Common Name, Classification:
Trade Name: Skeletal Dynamics Sterilization Trays

Classification Name: Sterilization wrap containers, trays, cassettes and other accessories (21 CFR §888.6850)

Common Name: Sterilization Cassettes, Instrument Tray, Sterilization Tray, Instrument Delivery System

Class: Class II (KCT)

Predicate Devices:
Smith & Nephew Instrument Tray – K090562
Riley Medical, Inc. MetaPak Multi-Purpose Instrument Tray – K993535

Description of the Device:
Skeletal Dynamics Sterilization Trays are designed to contain Skeletal Dynamics reusable medical devices during transport, sterilization and storage and to allow optimal exposure of the tray's contents to sterilant during the sterilization process. The trays are intended ONLY for use with Skeletal Dynamics medical devices. The trays must be used in conjunction with an FDA cleared sterilization wrap in order to maintain the sterility of the contents.

The trays are different sizes of the same basic configuration and consist of a rectangular base with a lid that fastens to the base with latches. The trays have perforations on the lid, base bottom and sides. Insert trays with custom made brackets

can be used to organize instruments and hold caddies in which smaller components are stored. The insert trays and caddies facilitate organization, storage and transport. They also contain perforations to allow optimal exposure of the tray's contents to sterilant during the sterilization process.

Intended Use:
Skeletal Dynamics Sterilization Trays are intended to contain Skeletal Dynamics reusable medical devices for convenient organized storage, sterilization and transport between usages. The full Din and half DIN trays include as accessories an insert to hold instruments and a caddy to hold implants and smaller components. The Akro-Vu tray only contains brackets to hold the Akro-Vu System's reusable components.

The full DIN and half DIN trays are suitable for use in both pre-vacuum steam and high temperature gravity steam sterilization methods. The Akro-Vu tray is suitable for use in pre-vacuum steam sterilization method. The trays are not intended to maintain sterility; they are intended to be used with a validated sterilization wrap in order to maintain the sterility of the enclosed devices.

Validated Sterilization Parameters for full DIN and half DIN trays:

Method	Temperature	Exposure Time	Drying Time
Pre-vacuum steam	270°F	4 minutes	20 minutes
High Temperature Gravity Steam	270°F	15 minutes	20 minutes

Validated Sterilization Parameters for Akro-Vu tray:

Method	Temperature	Exposure Time	Drying Time
Pre-vacuum steam	270°F	4 minutes	20 minutes

Device models that are the subject of this pre-market notification:

Reference	Description	Dimensions (L x W x H)
TRAY-STT-CBF1	Tray, Sterilization Full Din (Align)	19in x 9.5in x 3.6in
TRAY-STT-CBH1	Tray, Sterilization Half Din (Implate)	9.7in x 9.7in x 3.6in
AKR-CTR-CBC1	Tray, Sterilization Akro-Vu	15in x 12in x 4in

Comparison of Technological Characteristics to Predicate Devices:
The Skeletal Dynamics Sterilization Trays have the same technological characteristics as the predicates. They are all used for storage, transport and sterilization of reusable medical devices between uses. The full DIN and half DIN trays are suitable for use in both pre-vacuum steam and high temperature gravity steam sterilization methods. The Akro-Vu tray is suitable for use in pre-vacuum steam sterilization method. They are substantially equivalent in material, design and intended use to the predicate devices. The subject trays do not incorporate any new technological characteristics. There are no significant differences between the proposed and predicate devices that raise new questions of safety or effectiveness.

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Performance Testing:
Performance testing was conducted which confirmed that sterilization was achieved to the validated sterilization parameters above indicated for all three device models in pre-vacuum steam sterilization process, and for the full DIN and half DIN models in gravity steam sterilization process.

Conclusion:
We believe the subject device is substantially equivalent to the predicate device and conclude that the subject device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 25 2011

Ms. Ana M. Escagedo
Vice President
Skeletal Dynamics, LLC
8905 SW 87th Avenue, Suite 201
Miami, Florida 33176

Re: K102103
Trade/Device Name: Skeletal Dynamics Sterilization Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: December 1, 2010
Received: December 3, 2010

Dear Ms. Escagedo:

This letter corrects our substantially equivalent letter of December 7, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

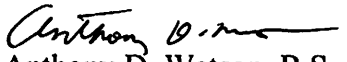
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K102103

DEC - 7 2010

Device Name: Skeletal Dynamics Sterilization Trays

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Prescription Use _____ AND/OR Over-The-Counter Use __x__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

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Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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